



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,005	06/28/2001	Hakuo Ikegami	IKEGAMI=2	6398

7590 07/01/2003

BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
Washington, DC 20001-5303

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
1638	13

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/893,005	IKEGAMI ET AL.
Examiner	Art Unit	
Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11-30 is/are pending in the application.

4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 February 2003, Paper No. 9, has not been entered. Applicant's Reply, filed 10 April 2003, Paper No 12, has been entered.

Status of the Claims

2. Applicant has canceled claims 1-10, and added new claims 11-30. Claims 11-30 are pending. Claims 22-30 are nonelected, as discussed below. Claims 11-21 are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

5. Newly submitted claims 22-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions I (claims 11-21) and II (claims 22-30) are related as product and process of use. The

inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product; the transgenic plants can be used for molecular farming to produce and isolate the protein of interest.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected as being directed to non-statutory subject matter: Claim 18 is drawn to an isolated tissue of a transgenic plant. An isolated tissue of a transgenic plant is not necessarily transgenic, and thus would encompass tissues from an untransformed plant. Since the tissue has not been produced under selective conditions, the tissue is not necessarily transgenic. Rather this tissue would be identical to the wild-type tissue, which is a product of nature.

Claim Rejections - 35 USC § 112 second paragraph

7. Claims 11-21 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

In claim 11, "obtainable" should be replaced by "obtained", since no conditions are set forth for "obtainable". It is unclear how a "plant body" differs from a "plant". "In an amount effective" is unclear. Effective for what? Does this refer to an expression level, or to an amount of plant body taken orally? Diseases "susceptible to" is unclear. Is the protein the cause or the treatment of the disease? "also" should be inserted in front of "endogenously". The method set forth in claim 11 does not produce a transgenic plant. It is unclear how step (iii) results in a transgenic plant.

Claim 11 seems to place humans and mammals in different categories, however claim 12 is drawn to mammalian cytokines. Does this exclude human cytokines?

Does claim 14 mean that any mammalian source can be used to treat any mammalian disease? Human interferon is not equivalent to mouse interferon, for example.

In claim 15, "edible" plant is unclear because this necessarily refers to an organism for which the plant is an edible foodstuff. For instance, some plants are edible to cattle (ruminants) and not to human.

In claim 17, "added" is ambiguous. At what stage is the trehalose added? Does "added" mean transgenic?

In claims 20 and 21, what does "processed" mean? Applicant gives a list of processes, but does not state what is kept and what is discarded from any given step.

For example, "extracting": if a plant is extracted by lyophilization, removing the water, and leaving the dehydrated plant material, the water removed is a product of the extraction. Is this Applicant's intent?

In claim 11, "physiologically active proteins" remains rejected, for reasons of record.

Applicant traverses primarily stating: that this term has been defined on page 3 bridging to page 4 of the specification. And that this is a commonly used term as evidenced by use of the term in the cited and applied Goodman patent US 4,956,282.

Applicant traversal has been considered and is unpersuasive, because the definition given by applicant does not specify what it is about "physiologically active proteins" that distinguishes them from other proteins. The use of the term by Goodman does not clarify the term in the instant case. Introducing definitions from another patent, and Applicant saying that definition is what he meant, is not persuasive because the Specification must be clear and concise, an enabled as of the time of filing. Goodman is not an authoritative text and does not provide the requisite definition to clarify this phrase.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 112, first

8. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. The rejected subject matter is "nerve growth factor, epidermal growth factor, platelet derived growth factor, transforming growth factor alpha, growth factor beta, growth hormone, insulin and steroids". Applicant is invited to point out the page and line number in the specification where "nerve growth factor, epidermal growth factor, platelet derived growth factor, transforming growth factor alpha, growth factor beta, growth hormone, insulin and steroids" can be found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

9. Applicant, in the Rely of 23 April 2003, traverses, stating primarily that the Examiner indicated in the Advisory Action dated March 25, 2003, that the recitation of "grown-up" in the amendment after final rejection of December 24, 2002, is new matter. Applicants disagree and drawn Examiner's attention to page 20, first full paragraph, and page 23, second full paragraph, where "grown-up" is fully supported. Applicant's traversal has been considered and is unpersuasive because the amendment after final rejection of December 24, 2002 has not been entered. Furthermore, the recitation in question, "grown-up", does not appear in Applicant's cited support in the specification.

Claim Rejections - 35 USC § 102

10. Claims 11-20 remain rejected under 35 USC 102 (b) as being anticipated by Goodman, et al (US #4, 956, 282, issued September 11, 1990), for reasons of record.

Applicant traverses, stating primarily: that Goodman teaches the use of plant cells as biological factories, whereas Applicant teaches the use of transgenic plants for oral administration.

Applicant traversal has been considered and is unpersuasive, because the intended use has no patentable weight in the claim. These claims are drawn to a product and not to a method using. Goodman does not indicate that the transgenic plant produced cannot be administered orally. Rather, Goodman teaches ingestion of edible plant parts (col 5, lines 51-60) containing the physiologically active protein.

Applicant further traverses, stating primarily: particular levels of pharmacologically active proteins when produced in plants are more effective than the same pharmacologically active protein, isolated and used.

Applicant traversal has been considered and is unpersuasive, because the claims are not drawn to any particular level of expression. Applicant's arguing specific levels is not commensurate to the scope of the claims.

Accordingly Goodman anticipates the claimed invention.

11. Claim 21 is rejected under 35 USC 102 (b) because a plant containing trehalose appears to be an inherent property of the claimed transgenic plants. Plants, especially *Brassica*, are known to produce trehalose naturally (Vogel et al, *J Exper. Botany*. 52, 1817-1826, 2001), as discussed in Office Action of 3 May 2002, page 4.

Accordingly, Vogel anticipates the claimed invention.

REMARKS

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer
Patent Examiner
Art Unit 1638
June 27, 2003

Phuong Bui
PHUONG T. BUI
PRIMARY EXAMINER 6/27/03